DME INSPECTION REPORT
North Carolina Board of Pharmacy
Investigations and Inspections

6015 Farrington Rd. Suite 201
Chapel Hill, NC 27517-8822
919-246-1050

Firm Name:	**Permit:**	**Date:**	**Case #:**
Address:	**Person Providing Info:**		
	PIC:		
Hours of Operation:			

S	U	N/A	INSPECTION ITEMS	COMMENTS
○	○	○	**1)** GS 90-85.23 - Permit posted conspicuously in the facility.	
			Device and Medical Equipment Permits	
○	○	○	**2)** 46.1608(a)(1) - Adequate qualified personnel to properly render services in a manner prescribed by law.	
○	○	○	46.1608(a)(3) - If disp. Medical O_2, must ensure (A) 24hr back up; (B) O_2 analyzer @ facility, if concentrations are disp.	
○	○	○	46.1608(a)(4) - Suitable facility for inventory, fabrication work space, and record retention.	
○	○	○	46.1608(a)(5) - Copy of the pharmacy laws of NC, Pharmacy Practice Act, and current copy of the rules and regulations in the pharmacy.	
○	○	○	46.1608(a)(6) - Functioning lavatory with hot/cold running water or hand washing appliances or waterless hand cleaner.	
○	○	○	46.1608(a)(7) - Clean, orderly, and sanitary.	
○	○	○	46.1608(a)(8) - Services applicable to its customer base.	
○	○	○	46.1608(a)(11) - Essential services available 24 hours 7 days a week.	
○	○	○	46.1608(a)(12) - Maintain written procedure at location for handling complaints.	
○	○	○	46.1608(a)(13) - Compliance with local and state fire and building laws.	
○	○	○	46.1608(a)(14) - Compliance with OSHA requirements, including Universal Precautions.	
○	○	○	46.1608(b) - Permit must be countersigned by the person in charge.	

S	U	N/A	INSPECTION ITEMS	COMMENTS
○	○	○	**3)** 46.1804(a) - Device dispensing and medical equipment delivery occurs only by bona fide employees.	
○	○	○	**4)** 46.1806 (c) - Records retained for three (3) years.	
○	○	○	**5)** 46.1806(i) - Transfer of orig. rx info. for refill is permissible b/t device & med equip holders as transferring permit holder provides all records necessary for disp & does not interfere w/ the svc. & claims process of receiving permit holder.	
○	○	○	**6)** 46.1809(4) - Record of emergency dispensing/delivery of devices/ medical equipment and prescriber notified.	
○	○	○	**7)** 46.2504(a)&(c) - Pt. Counseling: name, description, purpose of device/ equipment, route dosage, administration, continuity of service, special directions, side effects, interactions, self monitoring techniques, proper storage, refill information, patient name, address, telephone number, DOB, gender, and medical history.	
○	○	○	46.2504(b) - Toll free telephone service is required when a registrant's primary population is not accessible through a local exchange. Proficiency in explaining and demonstrating the safe and proper use of devices and equipment and for documenting the demonstration of such proficiency.	
○	○	○	46.2504(d) - Information for counseling kept current.	
○	○	○	46.2504(g) - Records retained for three (3) years	
○	○	○	46.2504(h) - Documentation that written notice of warranty was given to the patient concerning service after the sale.	
			Devices	
○	○	○	**8)** 46.2602 - Devices shall be dispensed to outpatients only pursuant to an order from a practitioner.	
○	○	○	**9)** 46.2603 - Educated and trained sufficiently in safe and proper delivery of medical equipment.	
○	○	○	**10)** 46.2604(a) - Device and medical equipment order must comply with Board Rules 2301-2305 and shall be maintained at the dispensing site. Serial numbers shall be maintained as part of the records.	
○	○	○	46.2604(b) - Records retained for three (3) years.	
○	○	○	46.2604(c) - File copy of every item sold or rented with serial number or tracking number or code in compliance with FDA Medical Device Tracking requirements.	
○	○	○	**11)** 46.2606 - Convey warnings issued by government agencies and manufacturers.	
			Rehabilitation Equipment	
○	○	○	**12)** 46.2609(b)(1-3) - Solicitation of results of assessments and evaluation. Choice of commercial vs. custom equipment. Measurements of Patients and Clients. Documenting goals and objectives.	
○	○	○	46.2609(b)(5) - Instruct patient and family in safe and proper use and care of equipment.	

S	U	N/A	INSPECTION ITEMS	COMMENTS
○	○	○	**Cont.** **12)** 46.2609(b)(6) - Provide service and support and within 72 hours provide a response to a patient request.	
○	○	○	46.2609(b)(7) -Documentation that written notice of warranty was given to the patient concerning service after the sale. Provide specific written statement of warranty on the equipment provided, including commercial warranties and those for adapted or custom fabricated items.	
○	○	○	46.2609(b)(8) - Liability insurance of at least 1,000,000.	
○	○	○	46.2609(b)(9)(A) - Compatibility and safety of interfacing techniques of custom fabricated parts with commercially available equipment.	
○	○	○	46.2609(b)(9)(B) - Understanding the properties of the materials being used in custom designed and modified equipment to assure long term durability.	
○	○	○	46.2609(b)(9)(C) - Documenting goals and objectives of the referring medical or education personnel, as well as short and long term effectiveness of the equipment in meeting those goals and objectives.	
○	○	○	46.2609(b)(9)(D) - Complaints and problems, including complaint file.	
			Medical Gas, Oxygen & Respiratory Equipment	
○	○	○	**13)** 46.2610(a)(2) - Comply with all DOT regulations if transporting medical gases.	
○	○	○	46.2610(a)(3) - Comply with FDA and all state agency requirements regarding transfilling and repackaging if transfilling.	
○	○	○	46.2610(a)(4) - Demonstrate that O2 provided in cylinder or liquid form meets minimal purity standards for medical grade O2.	
○	○	○	46.2610(a)(6)(A) - Demonstrate that each piece of equipment has been checked, is free of defect, and operates within manufacturer's specifications.	
○	○	○	46.2610(a)(6)(B) - Refrain from modifying equipment to the extent that the modification might reasonably cause harm.	
○	○	○	46.2610(a)(6)(C) - Maintain all electrical components so they do not present a fire or shock hazard.	
○	○	○	46.2610(a)(6)(D) - Ensure that all appropriate warning labels or labeling, including tags are present on the equipment provided.	
○	○	○	46.2610(b)(1) - Ensure that lot numbers and expiration dates are affixed to each cylinder delivered.	
○	○	○	46.2610(b)(2) - Maintain a tracking system for all medical oxygen and gas delivered.	
○	○	○	46.2610(b)(3) - Document all equipment serial numbers and model numbers to ensure that equipment can be retrieved if a recall is initiated.	

S	U	N/A	INSPECTION ITEMS	COMMENTS
○	○	○	**Cont.** **13)** 46.2610(b)(4) - Maintain records for equipment that requires FDA tracking.	
○	○	○	46.2610(c)(1) - Function and safety check prior to set up.	
○	○	○	46.2610(c)(2) - Protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens.	
○	○	○	46.2610(c)(3) - Maintain a Material Safety Data Sheet on file for solutions and products used in cleaning and disinfecting procedures.	
○	○	○	46.2610(c)(4) - Maintain segregated areas for clean, dirty ,and contaminated items.	
○	○	○	46.2610(c)(5) - Clean and disinfect equipment according to manufacturers' specification.	
○	○	○	46.2610(c)(6) - Instruct the patient on proper cleaning techniques as specified by the manufacturer.	
○	○	○	46.2610(d)(1) - Problem reporting, tracking, recall, and resolution.	
○	○	○	46.2610(d)(2) - Performance of service as specified by the manufacturer and the documentation of such performance in the service records.	
○	○	○	46.2610(d)(3) - Routine inspection, service, and maintenance of equipment located in the patient's home according to manufacturer's specifications.	
○	○	○	46.2610(e)(1-7) - Equipment suppliers shall maintain repair logs to document repairs and maintenance of equipment. Documentation must include type of equipment, manufacturer, model, serial number, date of repair, type of repair, who performed the repair.	
○	○	○	46.2610(f) - Maintain testing equipment to ensure accurate calibration.	
○	○	○	46.2610(g) - Written policy for handling complaints and problems, which include complaint file.	
○	○	○	46.2610(h)(1)(A-E) - Counseling requirements, Orientation checklist, instructions, safety, precautions, cleaning procedures, maintenance procedures, and return demonstrations on back up O2 systems. Plan of Service.	
○	○	○	46.2610(h)(2) - Instruct patients about routine & emergency contact procedures.	
○	○	○	46.2610(h)(3) - Review written instructions to properly operate equipment.	
			Medical Equipment	
○	○	○	**14)** 46.2611(a)(1-3) - Solicitation of results of assessments and evaluation. Choice of commercial vs. custom equipment. Measurements of Patients and Clients. Documenting goals and objectives.	

S	U	N/A	INSPECTION ITEMS	COMMENTS
○	○	○	**Cont.** **14)** 46.2611(a)(4) - Deliver, fit, and adjust the prescribed equipment.	
○	○	○	46.2611(a)(5) - Instruct patient and family in safe and proper use and care of equipment.	
○	○	○	46.2611(a)(6) - Provide service and support and within 72 hours provide a response to a patient request.	
○	○	○	46.2611(a)(7) - Liability insurance of at least 1,000,000.	
○	○	○	46.2611(a)(8) - Demonstrate that each piece of equipment has been checked, is free of defect, and operates with in the manufacturers' specifications.	
○	○	○	46.2611(a)(9) - Refrain from modifying equipment to the extent that the modification might reasonably cause harm.	
○	○	○	46.2611(a)(10) - Maintain all electrical components so they do not present a fire or shock hazard.	
○	○	○	46.2611(a)(11) - Ensure that all appropriate warning labels or labeling, including tags are present on the equipment provided.	
○	○	○	46.2611(a)(12) - Function and safety check prior to set up.	
○	○	○	46.2611(a)(13) - Protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens including procedures to prevent cross-contamination.	
○	○	○	46.2611(a)(14) - Clean and disinfect equipment according to manufacturers' specification.	
○	○	○	46.2611(b)(1) - Problem reporting, tracking, recall, and resolution.	
○	○	○	46.2611(b)(2) - Performance of service as specified by the manufacturer and the documentation of such performance in the service records.	
○	○	○	46.2611(b)(3)(A-G) - Equipment suppliers shall maintain repairs logs to document repairs and maintenance of equipment. Documentation must include type of equipment, manufacturer, model, serial number, date of repair, type of repair, who performed the repair.	
○	○	○	46.2611(c)(1) (A-E) - Counseling requiremetns, orientation checklist, instructions, safety, precautions, cleaning procedures, maintenance procedures, and return demonstrations on equipment delivered.	
○	○	○	46.2611(c)(2) - Instruct patient about emergency & routine contact procedure.	
○	○	○	46.2611(c)(3) - Written instructions to properly operate equipment.	
○	○	○	46.2611(c)(4) - Plan of Service.	

Notes

Inspector Signature: _____ Date: _____

☐ By Checking this box, I acknowledge that by my signature I have reviewed this inspection report with the investigator.

Person In Charge Signature : _____ Date: _____

Email Address: _____